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**NEW UTILITY PATENT APPLICATION
TRANSMITTAL
(Large Entity)**

(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))

Docket No. S63.2-7531

Total Pages in this Submission

(including checks and postcard)

35

jc490 U.S. PTO
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Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled: PROTECTIVE COATINGS FOR MEDICAL DEVICES

and invented by: Jason T. Lenz

If a CONTINUATION APPLICATION, check appropriate box and supply the requisite information:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: __

Enclosed (in addition to the 4 pages of this transmittal) are:

4 pages

Application Elements

1. ☒ Filing fee as calculated below:

a. ☐ filing fee is NOT ENCLOSED - fee will be paid at the time of responding to the Notice of Missing Parts -- DO NOT CHARGE DEPOSIT ACCOUNT

b. ☒ a check in the amount of \$760.00 to cover the filing fee is enclosed.

1 page

c. ☐ charge to Deposit Account as authorized at Item 2(a) on next page.

FEE CALCULATION AND CLAIMS

For	No. Filed	No. Allowed	No. Extra	Rate	Fee
Total Claims	20	- 20 =	0	x \$18.00	\$ 0.00
Indep. Claims	3	- 3 =	0	x \$78.00	\$ 0.00
BASIC FEE					\$760.00
TOTAL FILING FEE					\$760.00

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2. The Commissioner is hereby authorized to charge and credit Deposit Account No. 22-0350 as described below. A duplicate copy of this sheet is enclosed.

- a. ☐ Charge the amount of \$____ as filing fee.
- b. ☒ Credit any overpayment.
- c. ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- d. ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

3. ☒ Specification having 16 pages and including the following: 16 pages

- a. ☒ Application Cover Sheet - 1 page
- b. ☒ Descriptive Title of the Invention -
- c. ☐ Cross References to Related Applications *(if applicable)*
- d. ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
- e. ☐ Reference to Microfiche Appendix *(if applicable)*
- f. ☒ Background of the Invention
- g. ☒ Brief Summary of the Invention
- h. ☒ Brief Description of the Drawings *(if applicable)*
- i. ☒ Detailed Description
- j. ☒ Claim(s) as Classified Below - 2 pages
- k. ☒ Abstract of the Disclosure -1 page

4. ☒ Drawing(s) *(when necessary as prescribed by 35 U.S.C. 113)* 4 sheets 4 pages

5. ☒ Oath or Declaration - 3 pages

- a. ☒ Newly executed *(original or copy)* ☐ Unexecuted
- b. ☐ Copy from a prior application (37 C.F.R. 1.63(d)) *(for continuation/divisional application only)*

6. ☒ Separate Power of Attorney 1 pages

- ☐ 37 C.F.R. 3.73(B) Statement *(when there is an assignee and power of attorney is from assignee)*. It is hereby certified that the undersigned has authority to make this certification and has reviewed all the documents in the chain of title of the patent application identified herein and, to the best of undersigned's knowledge and belief, title is in the assignee identified in the accompanying Power of Attorney.

<p align="center">NEW UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity)</p> <p align="center"><i>(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))</i></p>	Docket No. S63.2-7531
	<p align="center">Total Pages in this Submission <i>(including checks and postcard)</i></p> <p align="center">35</p>

☐ Power of Attorney filed in parent application.

7. ☐ Incorporation by Reference *(usable if Box 5b is checked)*

The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 5b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

8. ☐ Computer Program in Microfiche *(Appendix)* _____ pages

9. ☐ Nucleotide and/or Amino Acid Sequence Submission _____ pages
(if applicable, all must be included)

- a. ☐ Paper Copy
- b. ☐ Computer Readable Copy *(identical to computer copy)*
- c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

10. ☒ Assignment Papers: 3 pages

- a. ☒ Assignment Recordation Cover Sheet (Form PTO 1595)
- b. ☒ Assignment
- c. ☒ A check in the amount of \$40.00 to cover the Recordal Fee
- d. ☐ Previously recorded on _____, Reel *, Frame *

11. ☐ English Translation Document *(if applicable)* _____ pages

12. ☐ Information Disclosure Statement: _____ pages

- a. ☐ PTO Form 1449 b. ☐ Copies of IDS Citations

13. ☐ Preliminary Amendment _____ pages

14. ☒ Acknowledgement Postcard 1 page

15. ☒ Form of Mailing - Express Mail *(Specify Label No.):* EL451220253US

16. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)* _____ pages

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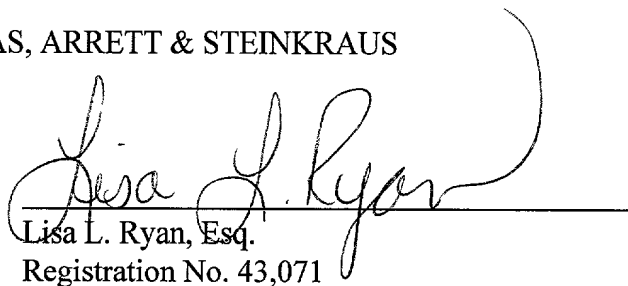
17. ☒ Additional Enclosures *(please identify below):* 2 pages
- ☒ Constructive Petition for Extension of Time and Fee Authorization Pursuant to 37 C.F.R. §1.136(a)(3) - 1 page
 - ☒ Correspondence Address form.
 - ☐ _____

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: January 4, 2000

By:



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DOCKET NO. S63.2-7531

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT**

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TITLE: PROTECTIVE COATINGS FOR MEDICAL DEVICES

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PROTECTIVE COATINGS FOR MEDICAL DEVICES

FIELD OF THE INVENTION

5 This invention relates to a method of providing a coating on a medical device, especially a dilatation balloon, which improves the durability of the device.

BACKGROUND OF THE INVENTION

Catheter devices having an inflatable balloon mounted at the distal end are
10 useful in a variety of medical procedures such as coronary angioplasty, stent delivery and placement for the opening of occluded or blocked blood vessels, for urological and reproductive surgeries, and to deliver biologically compatible fluids, such as radiologically opaque fluid for contrast x-rays to precise locations within the body. These procedures often involve the insertion of the device into blood vessels of
15 extremely reduced diameter for long distances through the vascular system. These applications require thin walled high strength balloons of a relatively inelastic or non-compliant nature that have predictable inflation properties.

Once the balloon is positioned at the desired location, it is inflated by supplying liquid under pressure through an inflation lumen to the balloon. The inflation
20 of the balloon causes stretching of a blood vessel, for instance, to reestablish acceptable blood flow through the blood vessel.

Balloon catheters are therefore produced from materials that can withstand high pressure, even at very low film thicknesses. The strength of the material is determined by measuring the tensile strength, and films with high strength relative to
25 film thickness are chosen. Examples of materials useful in balloon catheters include polyethyleneterephthalate (PET); polyether-polyester block copolymers such as the Hytrel® series of block copolymers, also referred to as thermoplastic polyester elastomers, available from Du Pont in Wilmington, DE or the Arnitel® series available from DSM, the Netherlands, such as Arnitel® 540; and polyamide/polyether/polyesters
30 such as PEBAX® 6333, 7033 and 7233. However, films produced from such materials tend to be harder, and to be scratch and puncture sensitive.

Scratches, abrasions, and even punctures can occur during handling and storage of the devices, or during use. Stents or other objects may scratch or puncture the balloon. Friction between the device and the vessel through which it is being passed can result in failure of the balloon at the weakened points that result from scratches,

5 abrasions or punctures. Lubricious coatings can reduce the friction between the device and the vessel wall, but provides only limited protection and does not really address the problem of scratches, abrasions and punctures. These coatings improve the success rate by altering the coefficient of friction between the device and the vessel wall, but do not address the scratch and puncture resistance other than by building film thickness.

10 Balloon failure at points of abrasions, scratches or punctures can be a problem during inflation. The balloon may prematurely burst, or the point at which the abrasion, scratch or puncture is located tends to be weaker, and when inflated, will have a tendency to over expand at that point, leading to over extension or bulging in the balloon wall at the weakened point. These bulges can in turn cause damage to blood vessels, for
15 instance. Over inflation is also a problem during stent delivery.

More compliant materials tend to be more scratch and puncture resistant, but do not provide the strength required to withstand the pressures used in some of these procedures. Non-compliance which is the ability to resist expansion beyond a predetermined size upon pressure, and to substantially maintain a profile, is required for
20 balloon catheters, especially those utilized in small vessels. Excessive expansion of more compliant materials can result in the rupture or dissection of blood vessels.

There is a continuing need in the medical device area to provide improved protective layers or coatings to balloons formed of noncompliant materials to increase the resistance of such balloons to scratches, abrasions and punctures. These improved
25 coatings provide increased resistance by building film thickness, but they do not address the issue of what occurs in the event that the balloon is scratched, abraded or punctured.

Efforts have been made to coat a balloon with a continuous coating of a thin durable material. The problem associated with such continuous coatings is that if a pinhole is present in the underlying balloon material, as the balloon is inflated, the
30 coating will also inflate, and at the point of the pinhole, can separate from the balloon material and form a bubble which can dissect an artery or vessel.

Specific examples of such problems occur with oriented PET which is commonly used for forming catheter balloons by a stretch blow molding method. The PET can exhibit pinholes that emit a high-velocity jet of inflation fluid during inflation. This then will result in the bulge forming in the outer coating layer which can cause
5 artery dissection. Pet also exhibits low tear resistance and does not take a crease.

One such method of improving the scratch or abrasion resistance of medical apparatuses is found in U.S. Patent No. 5,766,158 issued June 16, 1998 to Opolski which describes a protective surface coating for a medical device which contains a matrix polymer and a reinforcing agent to decrease the sensitivity of the medical
10 apparatus to injuries, such as scratches, punctures, and the like. The reinforcing agent is lamellar, platelet, or fiber-like in structure and has a higher surface hardness than the surface hardness of the medical apparatus.

SUMMARY OF THE INVENTION

15 It is an object of the present invention to provide a protective coating which improves the durability of a medical device, especially a dilatation balloon, and also addresses the problems which can arise if a scratch, abrasion or puncture occurs in, for instance, a balloon wall. The coating is noncontinuous in nature, thus preventing bubbling or aneurysms in the outer protective coating if the underlying device, i.e.
20 balloon wall, becomes damaged and allows inflation medium to escape.

The present invention further relates to a method of providing a dilatation balloon with improved durability comprising the steps of forming a balloon and applying a noncontinuous protective coating to said balloon. The coating comprises a polymeric material which gives the balloon improved durability.

25 The pattern of the coating may be a "waffle" pattern, a "strip" pattern, or a pattern having circular perforations, or any other pattern of a discontinuous nature.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a standard dilatation balloon in an uncoated
30 condition.

Fig. 2 is a perspective view of a standard dilatation balloon with a

"waffle" pattern coating of the present invention.

Fig. 3 is a perspective view of a standard dilatation balloon with a "stripe" pattern coating of the present invention.

Fig. 4 is a perspective view of a standard dilatation balloon with a
5 substantially solid coating having a uniform pattern of circular perforations.

Fig. 5 is a perspective view of a standard dilatation balloon having another embodiment of a "stripe" pattern coating and in an uninflated state.

Fig. 6 illustrates the same balloon as shown in Fig. 5 but now having pressure applied as during inflation. No aneurysm is exhibited.

10 Fig. 7 illustrates a balloon having a continuous coating of polyurethane polymer in its inflated state. An aneurysm is formed in the coating.

DETAIL DESCRIPTIONS OF THE PREFERRED EMBODIMENTS

The present coating may be utilized on any medical device which can be
15 damaged by scratching, abrasions, and/or punctures, especially catheter devices, and in particular, balloon catheters or dilatation balloons.

A dilatation balloon of the present invention is illustrated generally at 10 in Fig. 1, and includes an inflatable balloon 14 mounted at the distal end of an elongated flexible shaft 12. Balloon 14 has a balloon wall 13. Except as noted herein, catheter 10
20 is conventional in its construction, providing a lumen communicating with the interior of the balloon 14, for inflation and deflation of the balloon, and other optional features conventional in the dilatation catheter art. The balloon 10, has an inflated configuration, illustrated in Fig. 1 and is made up of three main portions: the body 14, the cones 26 and the waist portions 28. Balloon catheters of this type are described in U.S. Pat. 5,490,839
25 to Wang et al. issued February 13, 1996 and herein incorporated by reference.

Fig. 2 illustrates the same balloon 14 coated with a "waffle" pattern coating 15 of the present invention coated over balloon wall 13.

Fig. 3 illustrates the same balloon construction with another embodiment of the coating 16 of the present invention having a different pattern than that exhibited in
30 Fig. 2. The pattern in this diagram is a "stripe" pattern wherein the stripes run diagonally around the circumference of the balloon.

Fig. 4 illustrates the same balloon construction as in Figs. 2 and 3 with yet another embodiment of a the coating 17 of the present invention having yet a different pattern than exhibited in the other figures. This embodiment illustrates a more solid coating which has circular perforations spaced at a uniform distance from one another.

5 The size of the perforations may be varied.

Fig. 5 illustrates a balloon 20 in its uninflated state, and having a "stripe" pattern coating 18 of a polyurethane polymer, also referred to as a "shape memory polymer." This pattern of has the stripes running longitudinally with the balloon whereas the pattern illustrated in Fig. 3 exhibits stripes running diagonally around the

10 circumference of the balloon 20. The polyurethane polymer utilized in this embodiment is available from Mitsubishi Heavy Industries, Ltd in Tokyo, Japan, under the tradename of SMP-3510. The balloon 20 has an inner wire lumen 30 for delivery of the inflation media. The balloon exhibits a pinhole 50 left of center and beneath a coated section of the balloon.

15 Fig. 6 illustrates the same balloon 20 as shown in Fig. 5 during inflation. Inflation medium can be seen venting from out the edges of the coated section. Desirably, no aneurysm is formed in the coating because the inflation medium can easily escape. The inflation media 55 is exiting through the pinhole 50 and can be seen venting out the sides of the discontinuous stripe coating 18 on balloon 20. The large inverted

20 water droplet 60 seen in the center from of the photograph is forming as a result of the inflation media 55 flowing out of the pinhole 50. Both the stream of inflation media 55 and the droplet 60 are on the same side of the balloon 20. Such droplet formation would not be exhibited were the balloon in an aqueous environment such as a vessel of a patient but such fluid would be carried away in the blood.

25 Fig. 7 illustrates a balloon 20 having a continuous coating 19 of polyurethane polymer, SMP-3510, available from Mistubishi Heavy Industries, Ltd, in its inflated state. An aneurysm 40 is formed in the coating. Inner wire lumen 30 is for inflation media delivery.

While these are some suggestions as to types of patterns that may be used

30 in the coating method of the present invention, there are a limitless variety of patterns and sizes of patterns that may be utilized to achieve the objectives of the present

invention. Any pattern wherein there is discontinuity in the coating, may alleviate the formation of pinholes which may ultimately lead to aneurysms in the balloon construction, and to damage to the patients vessels.

The balloons may be constructed of thermoplastic polymeric materials including thermoplastic elastomers, i.e. block copolymers; copolymers and terpolymers of ethylene; homopolymers, copolymers and terpolymers of propylene; ethylene α -olefins; polyesters; polyamides; polyurethanes; polycarbonates, vinyl copolymers; ionomer materials and so forth. More specifically, materials such as nylon, Selar®, polyether-polyester block copolymers (i.e. Hytrel® from DuPont or Arnitel® from DSM, Netherlands), Pebax® (polyether block amide copolymers), Surlyn®, polyethylene terephthalate, polytetrafluoroethylene, polyvinyl chloride, polyetherurethanes, polyesterurethanes, polyurethane ureas, polyurethane siloxane block copolymers, silicone polycarbonate copolymers, ethylene vinyl acetate copolymers, acrylonitrile-butadiene-styrene copolymers; polyphenylene sulfides; copolyesters or other similar extrudable thermoplastic, polymeric materials, or composites thereof may be utilized in the present invention. Thermosetting materials such as polyimides may also be utilized.

The balloon wall may be noncompliant or compliant. Noncompliant balloons are formed from relatively stiff materials including polyethyleneterephthalate (PET), high density polyethylene, polyamides, polycarbonates and stiff polyurethanes, and so forth. The balloon wall may also be compliant and made of materials such as polyvinyl chloride, polyethylene, polyester copolymers, polyolefin copolymers and so forth. The present invention provides a particular advantage when the balloon wall is made of a stiff, noncompliant material. Such materials tend to scratch more easily, especially if a fold occurs in the balloon.

Some specific preferred balloon materials include polyether block amides, such as Pebax® 7033 or 7233; polyester block ethers such as Arnitel® EM 40; polyethylene terephthalate (0.64 to 0.8 IV PET); and nylon. The formation of catheter balloons made of block copolymer elastomers where the hard segments are polyester or polyamide and the soft segments are polyether, is discussed in U.S. Pat. No. 5,556,383 issued September 17, 1996 to Wang et al. herein incorporated by reference. The formation of catheter balloons made of PET is discussed in U.S. Pat. No. 5,714,110 issued February 3, 1998 to

Wang et al. herein incorporated by reference. The formation of catheter balloons produced from block copolymer elastomers is discussed in U.S. Pat. No. 5,830,182 issued Nov. 3, 1998 to Wang et al., herein incorporated by reference.

A typical method of balloon formation involves first extruding a tubular preform, and subsequently blowing the tubular preform into a balloon. The balloon has what is referred to as a body, at least one cone portion, and at least one waist portion.

Suitable balloon forming techniques which may be employed are well known in the art and may be carried out in any conventional manner with conventional extrusion and blowing techniques. Such techniques for balloon formation are discussed in U.S. Patent No. 4,490,421 to Levy and in U.S. Patent no. 5,348,538 issued September 20, 1994 to Wang et al. herein incorporated by reference.

The balloon has a coating over the balloon wall. Preferably, the coating will be on the balloon body. However, the cones and the waist portion(s) may also be coated. Any thermoplastic polymeric material which is dissolvable in solvent, and which improves the durability of the balloon may be utilized. The coating polymer is desirably sufficiently flexible and elastic at body temperature and has only a minor, if any, impact on the compliance characteristics of the balloon. The coating material preferably does not adversely affect the compliance characteristics of the balloon itself. The polymeric coating may also preferably have some surface tack for certain applications including stent delivery catheters. A certain amount of tack may help hold the stent more securely when the stent is in the crimped down position.

The polymers may be thermoplastic or thermoset polymeric materials. Thermoplastic materials useful to the present invention include any type of material from which the balloons themselves may be produced, as well as many others. Examples of such materials include vinyl polymers, fluorinated and chlorinated polymers, polyolefins, polyurethanes, polystyrene, polyesters, nylons, polyamides, polycarbonates, polyacrylates, poly(meth)acrylates, copolymerized versions, and so forth. Rubbery block copolymers include those having the general configuration of linear, radial, star, Y-block, multiblock and so forth.

More specifically, the coating material may include polyvinyl chloride; polyethylene terephthalate; polyethylene homopolymers; styrene-butadiene-styrene block

copolymers; styrene-ethylene/butylene-styrene block copolymers; styrene-ethylene/propylene-styrene block copolymers; styrene-isoprene-styrene block copolymers; polyester elastomers, polyether-block amides; copolymers of ethylene and vinyl acetate, n-butyl acrylate, methylacrylate; interpolymers of ethylene and at least one
5 alpha-olefin; and so forth.

A preferred class of thermoplastic polymers useful for the coating are the thermoplastic polyurethane polymers.

Thermosetting polymers have functional moieties which are capable of crosslinking with other functional moieties.

10 Thermosetting materials include polyurethanes formed from an isocyanate and a polyol; acrylics; acrylates; methacrylates; epoxies; unsaturated polyesters; silicones having hydrolyzable acetate groups; polysulfides; cyanoacrylates; formaldehydes condensed with urea, phenol, resorcinol, melamine for instance, and so forth.

Thermosetting compositions refer to crosslinkable compositions, even those that do not
15 necessarily require elevated temperatures to initiate the chemical reaction. It is preferable to the present invention to initiate polymerization or cure using electron beam or ultraviolet radiation.

In a preferred embodiment of the present invention, a polyurethane polymer is utilized. The glass transition temperature of these polyurethane polymers
20 may be adjusted by changing the molar ratio of diisocyanate, polyol and chain extender. Glass transition temperatures may also be varied by changing the polyol itself. An example of a polyurethane polymer is SMP-3510 available from Mitsubishi Heavy Industries, Ltd. These polymers are also referred to as "shape memory polymers."

Water based polymers may also be utilized including polyurethane
25 dispersions and emulsion polymers such as acrylics, vinyl acetate homopolymers, vinyl acrylic copolymers, vinyl acetate ethylene copolymers, and so forth. A preferable water base coating is a urethane.

The coating of the present invention is a noncontinuous coating and may be referred to as a porous coating or pattern coating. Pattern coating can be achieved in a
30 number of ways including roll coating, screen printing, pad printing, spraying and so forth. In pad, roll or screen printing, the coating application head, i.e. roll or pad, for

instance, will have dimples or indentations which result in a noncontinuous coating being applied to the balloon. The pattern is preferably substantially uniform.

A preferable coating pattern which may be obtained using a pad printing method may be referred to as a waffle pattern wherein the shape of the indentation may be any shape provided the repeating pattern is substantially uniform. Typical indentation shapes are square or round. Such a pattern may be found in Fig. 2 or Fig. 3.

Spraying may also be employed to achieve a pattern type of coating to the balloon but will result in a much less uniform noncontinuous coating.

In the case of thermoplastic polymers, it will be preferable to first dissolve the polymer in a solvent or a blend of solvents prior to applying the coating to the balloon. Suitable solvents include acetone, methyl acetate, dimethylacetate, ethyl acetate, dioxane, alcohols, chloroform, methylene chloride, acetonitrile, toluene, methyl ethyl ketone, tetrahydrofuran, dimethylformamide, dimethylsulfoxide, cyclohexanone, acetates including butyl acetate, dimethylacetate, 1-methoxy-2-propanolacetate, and so forth, and mixtures thereof. The polymer may usually be dissolved in the solvent by shaking or by stirring at room temperature, but if necessary, an elevated temperature, such as about 40-50° C, may be utilized to dissolve the polymer. The coating thickness on the balloon may be adjusted by changing the concentration of the polymer solution. Typically, the concentration of polymer in solution will be about 1% to 60%, more preferably about 5% to about 55%, and most preferably about 10% to 50%. The concentration of the polymer in solution to some degree depends on the particular application with which the medical device will be coated. Some applications require lower viscosity solutions than others. For instance, spray applications may require polymer concentrations of about 10% to about 20% while pad printing may require higher polymer concentrations of about 20% to about 50%.

The solvent is then desirably evaporated from the coating, leaving only the polymer remaining. This may be accomplished either at ambient temperatures, or the evaporation process may be accelerated by drying at elevated temperatures.

Thermoplastic polymers become molten and flowable when subjected to heat. However, the polymers useful to the present invention preferably have high tensile strength. Such high strength polymers also typically have high molecular weights and

would require quite high temperatures of over 150° C to lower the viscosity enough to apply using conventional coating techniques. The balloon materials, being in thin film, would be sensitive to such high temperatures and it would therefore be detrimental to apply the coating to the balloon with high temperatures.

5 The coating is preferably applied when the balloon is in its inflated state. Coverage of the coating is preferably limited to the body of the balloon, and is not found on the waist or cone portions of the balloon. A particularly preferred method of application is pad printing. The pads are typically formed from a soft silicone rubber. Such materials would have less of a tendency to cause any abrasions in the balloon
10 material. The pad picks up the image or pattern to be printed from an etched plate, and then transfers the coating pattern to the balloon. Using this method, the coating may be wrapped around curved surfaces easily. The shape and design of the pattern can be easily varied. One preferred pattern may be referred to as a "waffle" pattern in which the coating actually resembles a waffle.

15 Film thickness of the coating is preferably from about 0.1 to about 3 mils, more preferably from about 0.1 to 1.5 mils, and most preferably from about 0.2 to 1 mil.

 The coating improves the durability of the balloon by making it more abrasion, scratch and puncture resistance. Furthermore, should an abrasion, scratch or puncture occur in the underlying balloon wall, the discontinuous nature of the outer
20 protective coating prevents it from inflating on its own and pulling away from the balloon wall, which in turn prevents bulging or bubbles which can cause dissection of blood vessels or arteries. A particular problem with the formation of such balloons is the occurrence of what is referred to in the industry as "pinholes." Inflation medium escapes through these pinholes causing the outer coating to inflate on its own forming a bulge or
25 bubble which can cause the dissection of a blood vessel of artery. The present invention overcomes such problems.

EXAMPLES

30 The following ingredients were utilized in preparing the coating composition for Example 1 and for Comparative Example A:

10% SMP-3510, polyurethane polymer available from Mitsubishi Heavy Industries, Ltd.
70% dimethylacetate (DMAC)
15% toluene
5% tetrahydrofuran (THF)

5

Example 1

The coating composition shown above was brushed on a dilatation balloon in a striped pattern. This pattern was accomplished by masking off sections of the balloon and brushing on the coating so that the masked sections had no coating. The coating was dried and the toluene, DMAC and THF were evaporated off leaving only the polyurethane, SMP-3510 on the balloon. The balloon, which had a pinhole in its wall, was then inflated. The pinhole was in the center of a coated section of balloon. The inflation medium flowed out of the pinhole and vented out of the sides of the coated section so that no aneurysm occurred in the coating.

15 Fig. 5 illustrates the coated balloon in its uninflated state. The pinhole is right of center and located beneath a coated section of the balloon. Fig. 6 illustrates the coated balloon in its inflated state. As can be seen from the illustration, the inflation medium is venting around the sides of the coating as desired. No aneurysm is formed in the coating.

20

Comparative Example A

A continuous coating of the composition shown above was brushed on a dilatation balloon. The coating was dried, evaporating off the toluene, DMAC and THF and leaving only the polyurethane, SMP-3510 on the balloon. The balloon had a pinhole in its wall, and upon inflation, a large bubble or aneurysm occurred in the coating as is shown in Fig. 7.

Example 2

A coating comprising a polyurethane polymer in a mixture of solvents available from Creative Materials under the tradename of CMI 118-43 was pad printed on a catheter balloon in a waffle pattern so as to eliminate the possibility of pinhole

4

[illegible]

CLAIMS:

1. An insertable medical device having a protective surface coating, said coating comprising a polymer selected from the group consisting of thermoplastic polymers and
5 thermosetting polymers and said coating being noncontinuous on said medical device.
2. The medical device of Claim 1 wherein said device is a dilatation balloon.
3. A dilatation balloon having improved durability formed from a thermoplastic polymer, said balloon having a non-continuous protective coating.
4. The dilatation balloon of Claim 3 wherein said balloon is formed from a polymer
10 selected from the group consisting of polyethylene terephthalate, high density polyethylene, polyamides, polyether block amides, polycarbonates, stiff polyurethanes, and mixtures thereof.
5. The dilatation balloon of Claim 3 wherein said coating comprises a polymeric material selected from the group consisting of thermoplastic polymeric and thermosetting
15 polymeric materials.
6. The dilatation balloon of Claim 3 wherein said coating comprises a polyurethane.
7. The dilatation balloon of Claim 3 wherein said noncontinuous coating is selected from the group consisting of a waffle pattern, a stripe pattern and a pattern having circular perforations.
- 20 8. The dilatation balloon of Claim 3 wherein said balloon is formed from a noncompliant material.
9. A method of providing a dilatation balloon with improved durability comprising the steps of:
 - a) forming a balloon wherein said balloon has a body, at least one cone
25 portion, and at least one waist portion; and
 - c) applying a noncontinuous protective coating to said balloon.
10. The method of Claim 9 wherein said balloon is formed by first extruding a tubular preform and blowing said preform into a balloon.
11. The method of Claim 9 wherein said noncontinuous coating is applied in a
30 pattern.
12. The method of Claim 9 wherein said pattern is selected from the group consisting

of a waffle pattern, a stripe pattern and a pattern having circular perforations.

13. The method of Claim 9 wherein said coating is applied by a pad printing method.

14. The method of Claim 9 wherein said coating is applied to said balloon body.

15. The method of Claim 9 wherein said balloon is formed from a non-compliant
5 thermoplastic polymer.

16. The method of Claim 9 wherein said balloon is formed from a thermoplastic
polymer selected from the group consisting of polyethylene terephthalate, high density
polyethylene, polyamides, polyether block amides, polycarbonates and stiff
polyurethanes, and mixtures thereof.

10 17. The method of Claim 16 wherein said balloon is formed from a thermoplastic
polymer selected from the group consisting of polyether block amides and polyethylene
terephthalate.

18. The method of Claim 9 wherein said coating is applied to said balloon as a
solution of the polymer in a solvent.

15 19. The method of Claim 9 wherein said coating comprises a polymeric material
selected from thermoplastic polymeric materials and thermosetting polymeric materials.

20. The method of Claim 10 wherein said coating comprises a polyurethane.

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PROTECTIVE COATINGS FOR MEDICAL DEVICES

ABSTRACT

5 This invention relates to a method of providing a coating on a medical device, especially a dilatation balloon, which improves the durability of the balloon.

Fig. 1

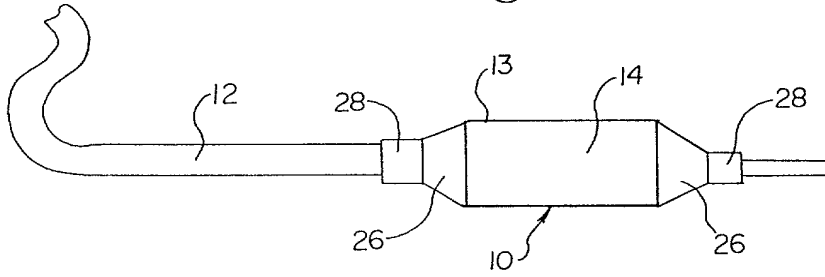


Fig. 2

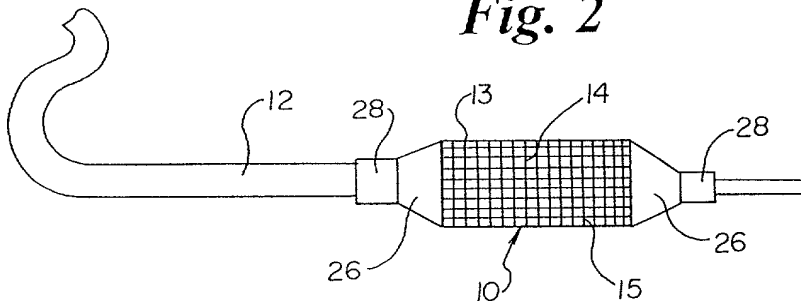


Fig. 3

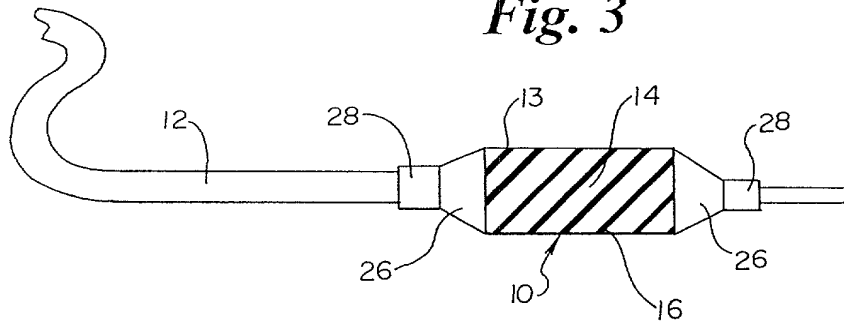


Fig. 4

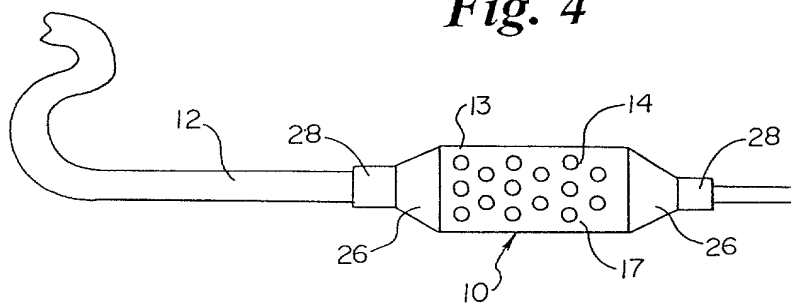


Fig. 5

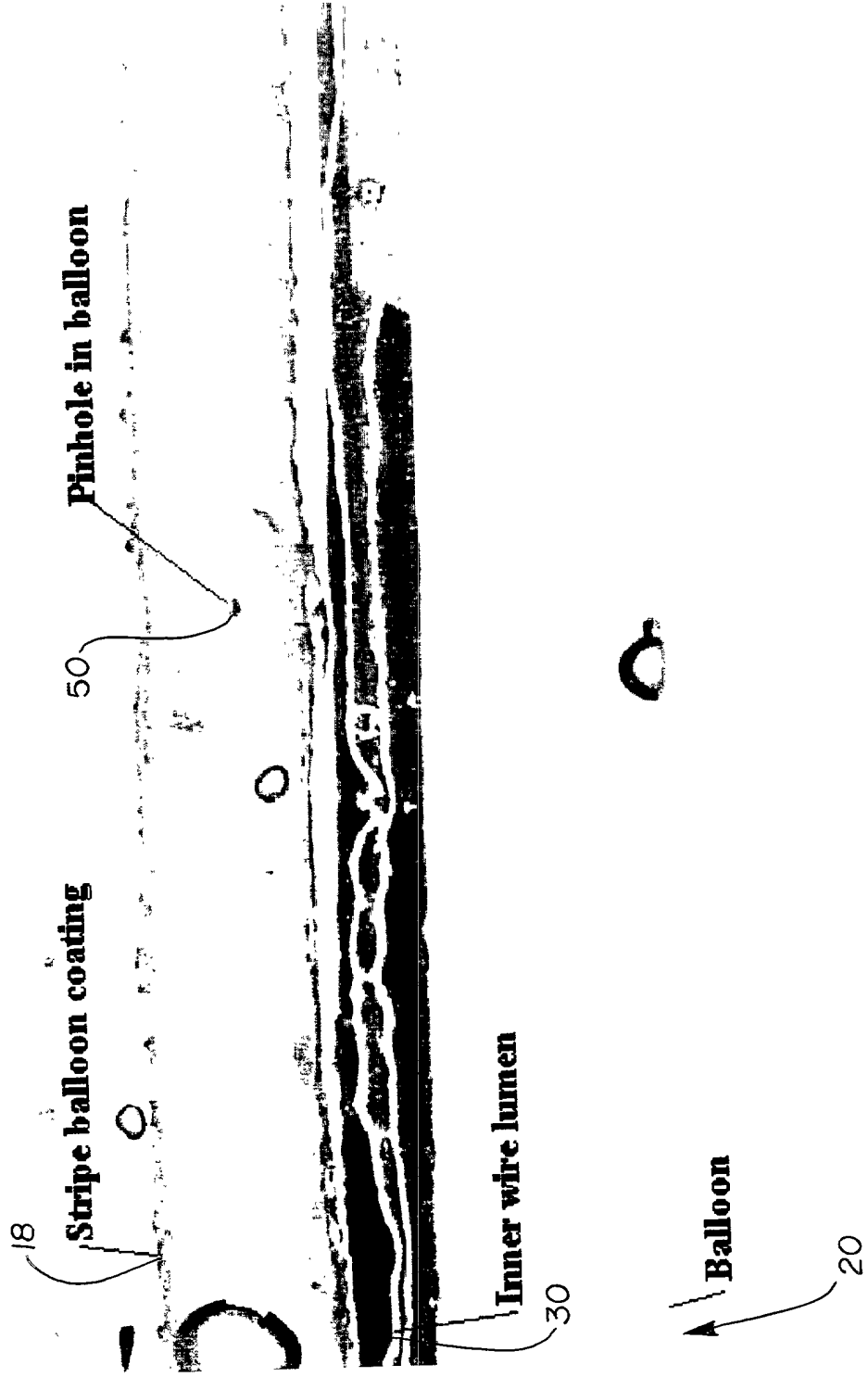


Fig. 6

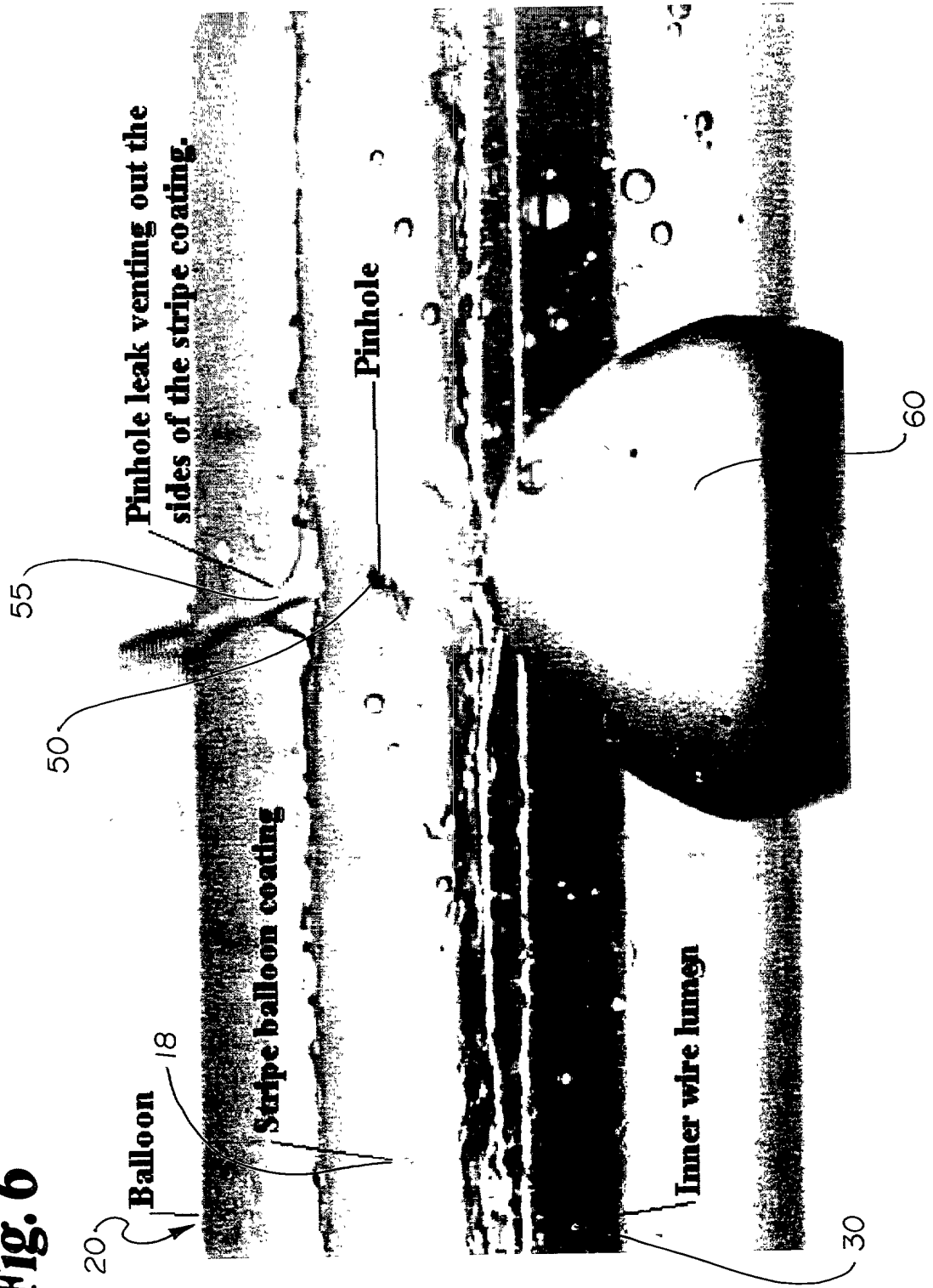
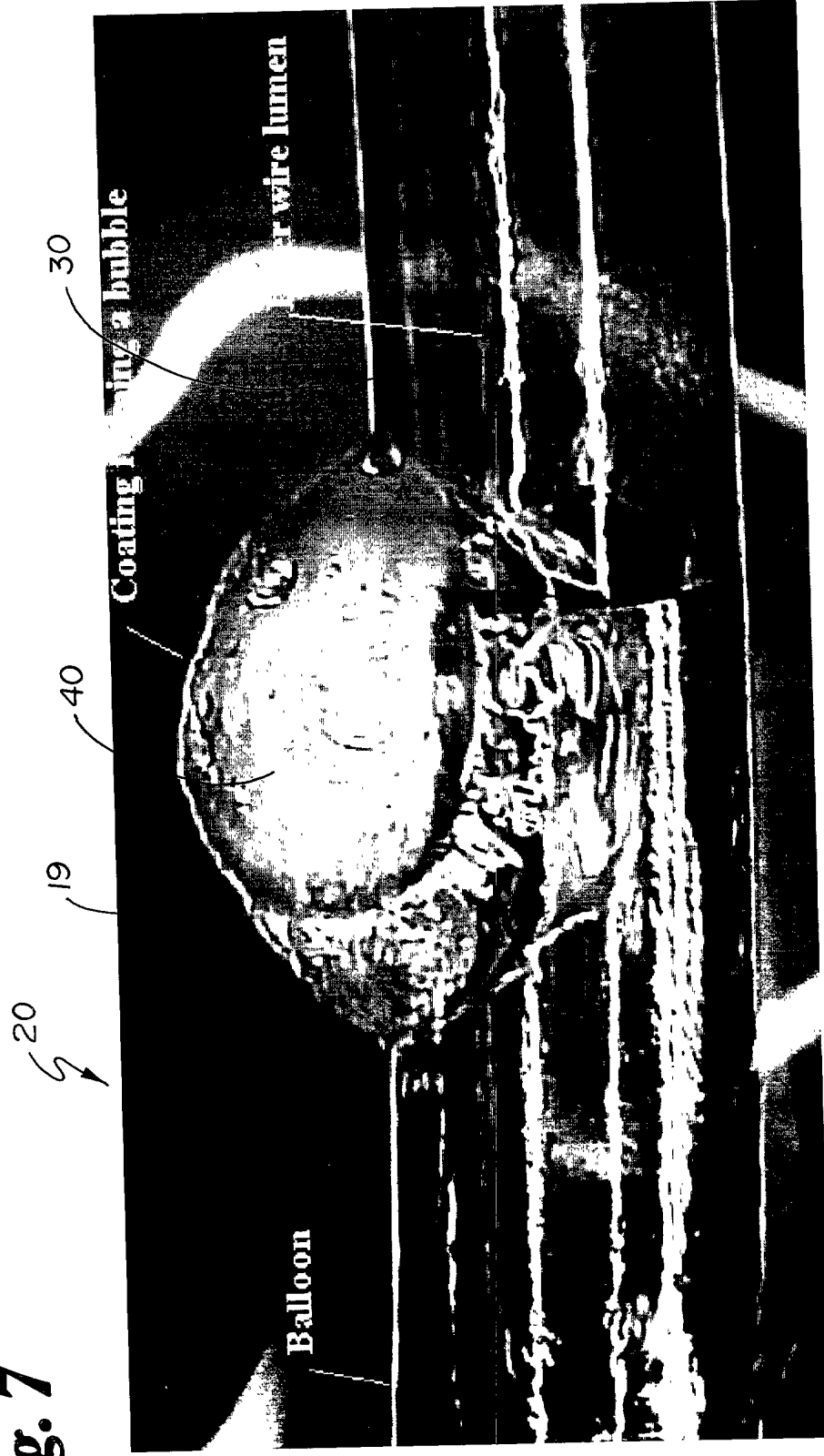


Fig. 7



DECLARATION

As a below-named inventor, I(we) hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

- ☒ original
- ☐ design
- ☐ supplemental
- ☐ national stage of PCT
- ☐ divisional
- ☐ continuation
- ☐ continuation-in-part (CIP)

INVENTORSHIP DECLARATION

My residence, post office address, and citizenship are as stated below next to my name;

I verily believe I am the original, first and sole inventor (*if only one name is listed below*) or an original, first and joint inventor (*if plural names are listed below*) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

PROTECTIVE COATINGS FOR MEDICAL DEVICES

the specification of which:

- a) ☒ is being filed concurrently herewith
- b) ☐ was filed on _____ and assigned Serial No. _____
- c) ☐ was filed as PCT International Application No. _____ filed on _____ and amended under PCT Article 19 on _____.

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56 including information occurring between the filing date of any prior application of which the present application is a continuation-in-part.

- ☐ In compliance with this duty there is attached an Information Disclosure Statement.
37 CFR 1.97.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d), of any foreign application(s) for patent or inventor's certificate or of any PCT international applications(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT international applications(s) designating at least one country other than the United States of America filed by me having the same subject matter having a filing date before that of the application on which priority is claimed.

- a) ☒ no such applications have been filed.
b) ☐ such applications have been filed as follows:

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

I hereby claim the benefit under Title 35 United States Code, §119(e) of any United States provisional application identified below.

- a) ☒ no such applications have been filed.
b) ☐ such applications have been filed as follows:

U.S. APPLICATIONS	
SERIAL NUMBER	U.S. FILING DATE
1.	
2.	

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. §120

I hereby claim the benefit under Title 35, United States Code, §120 of any United States applications(s) or PCT international applications(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior applications(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior applications(s) and the national or PCT international filing date of this application.

- a) ☒ no such applications have been filed.
b) ☐ such applications have been filed as follows:

U.S. APPLICATIONS	
SERIAL NUMBER	U.S. FILING DATE
1.	
2.	
PCT APPLICATIONS DESIGNATING THE U.S.	
PCT APPLICATION NO.	PCT FILING DATE
3.	

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No: S63.2-7531

Its:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Jason Lenz
Title:	PROTECTIVE COATINGS FOR MEDICAL DEVICES
Filed:	<input checked="" type="checkbox"/> concurrently herewith
	<input type="checkbox"/> on _____ and assigned Serial No. _____

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-7531

CORRESPONDENCE ADDRESS OF LAW FIRM

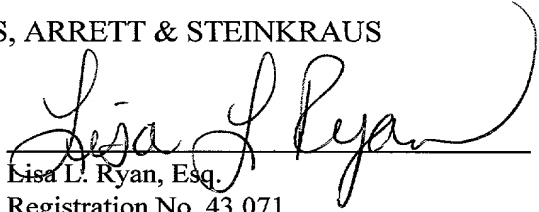
Vidas, Arrett & Steinkraus P.A. would like to make the following correspondence address of record. Please send all correspondence for this application to the address as follows:

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6109 Blue Circle Drive
Minnetonka, MN 55343-9131

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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